REMARKS

Claims 8-11 and 13-26 are pending. Claims 10, 11 and 13-26 are withdrawn from consideration, and claims 8 and 9 are rejected. Applicants appreciate that the rejection under 35 U.S.C. 112 is withdrawn in response to the last Amendment and Response.

Rejection under 35 U.S.C. 102

The Examiner maintains the rejection of claims 8 and 9 under 35 U.S.C. 102(b) as allegedly anticipated by Tang *et al.* (WO2001/066689). According to the Examiner, Tang *et al.* teach methods for treating cancer by administering a therapeutically effective amount of a composition comprising an antibody that binds to the KIAA0659 polypeptide (*citing*, page 4, lines 29-32 and pgs. 52-54). The Examiner says that SEQ ID NO: 340 is identical to SEQ ID NO:1 of the instant application. The Examiner adds that Tang *et al.* teach monoclonal, polyclonal, chimeric, humanized, and conjugated antibodies to a detectable label, cytotoxic agent or cytokine that specifically bind to the KIAA0659 polypeptide (*citing*, pages 74-84).

Applicants reiterate the explanations already submitted regarding Tang *et al.*

Applicants previously challenged the Examiner by explaining that Tang *et al.* do not enable a method to treat cancer. They present absolutely no data demonstrating clinical efficacy of an antibody for any cancer. Moreover, Tang *et al.* do not even teach or suggest an antibody to SEQ ID NO: 1 of the present application. The United States patent law is clear that a reference must enable the teachings that it alleges in order to serve as a proper prior art reference. However, the Examiner contends that the United States patent law states that what constitutes a proper enabling disclosure for a prior art reference is less than the standard for enablement for a patent application.

Recent case law clarifies that Tang *et al.* do not enable a method of treating any cancer

The Federal Circuit has recently addressed situations such as the instant rejection in *Impax Labs v. Aventis Pharmaceuticals* (Fed. Cir. 2008). A copy of the published case is submitted herewith as Exhibit A. To anticipate, the prior art must be enabling. That is, the prior art must "enable one of ordinary skill in the art to make the invention without undue experimentation." This enablement standard is admittedly different from a patent applicant's 35 U.S.C. §112 enablement requirement which requires enabling both *making and using* the invention. That distinction becomes lost in cases like the instant application and the patent at issue in *Impax Labs v. Aventis Pharmaceuticals*, however, where the claims cover a method of treatment. Here, the Federal Circuit requires anticipatory prior art to enable practicing the claimed method. Enablement of prior art is a question of law, but is based on underlying factual findings. In close cases, the important factual finding is the amount of experimentation that would have been necessary. Applying *Wands* factors, the Federal Circuit agreed that the prior reference at issue in *Impax Labs v. Aventis Pharmaceuticals* was not enabling, reasoning as follows:

> As shown by the trial court, the [prior art] '940 patent's dosage guidelines are broad and general without sufficient direction or guidance to prescribe a treatment regimen. The alleged prior art also contains no working examples. Finally, nothing in the '940 patent would have led one of skill in the art to identify riluzole as a treatment for ALS. In sum, each component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the '940 patent.

Applicants submit that in view of the Federal Circuit requiring more than providing a compound within a class of other compounds and providing only a general dosage parameter for a compound in order to enable a method of treating, Tang *et al.* cannot enable a method of treating lung or kidney carcinoma. Tang *et al.* merely teach the sequences of hundreds of proteins and speculate that the disclosed proteins may have any number of possible biological

activities. Tang *et al.* teach that the proteins may have a vast array of biological activities and uses including nutritional uses, cytokine and cell proliferation activity, stem cell growth factor activity, hematopoiesis regulating activity, tissue growth activity, immune stimulating or suppressing activity, activin/inhibin activity, chemotactic/chemokinetic activity, hemostatic and thrombolytic activity, cancer diagnosis and therapy, receptor/ligand activity, anti-inflammatory activity, leukemia treatment and nervous system disorder therapy. (*See,* pages 39 to 60). However, Tang *et al.* do not provide any data to support such a vast list of activities of the hundreds of proteins. Specifically, Tang *et al.* do not provide any data to support the protein encoded by SEQ lD NO: 340 for treating lung cancer or kidney cancer. Tang *et al.* teach every possible tissue or organ of the body which may be affected by cancer and speculate that the proteins may be useful for therapies. (See, page 53) However, none of the examples provide any supporting evidence. Further, there is even no indication in the examples that the sequences which were prepared from human tissues included cancer tissues. Still further, Tang *et al.* provide no specific dosage or therapy regimen, or delivery formulation or method for administering any of the subject proteins to effectively treat any cancer, much less lung or kidney carcinoma.

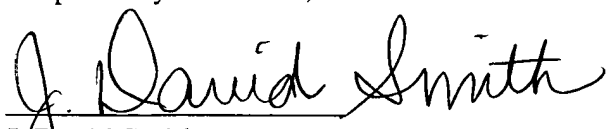
FEES

No fees are believed to be necessitated by the present Response. However, should any fees be due, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

CONCLUSION

Applicants submit that the foregoing comments place the application in condition for allowance. Withdrawal of the rejections is respectfully requested. If a discussion with the undersigned may be of assistance in resolving any remaining issues, the Examiner is invited to telephone the undersigned at (201) 487-5800, ext. 114.

Respectfully submitted,



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